

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 1 and 2 were pending in this application when last examined and stand rejected.

Claims 1 and 2 have been amended to address the formal matters in the Office Action. Support for amended claims 1 and 2 can be found in the disclosure, for example, at paragraphs [0006] to [0007] at pages 6-7, and Example 1 at paragraph [0014] on pages 10-11, see also, page 11, lines 1-3.

New dependent claims 4-8 have been added that further specify the nature of the lactoperoxidase and the digestion product thereof. Support can be found in the throughout the general disclosure, see for instance, paragraph [0007] at page 7, lines 10-15, page 9, lines 8-18, and Example 2 on page 11, lines 13-14. New independent claims 9 and 10 have been added that correspond to claims 1-2 but are in "consisting essentially of" format.

No new matter has been added.

Claims 1-10 are pending upon entry of this amendment.

II. INFORMATION DISCLOSURE STATEMENT

On page 2 of the Office Action, it was indicated that the IDS(s) filed February 1, 2006 and August 8, 2006 were not considered on the basis that Applicants did not provide legible copies of these documents in English to the Office.

Applicants respectfully disagree and submit that the references should have been officially considered by the Office, because copies of the references should have been forwarded to the USPTO by the International Search Authority pursuant to the trilateral agreement between the USPTO, EPO and JPO. Thus, the references should have been considered as they should be of record at the USPTO.

In addition, Applicants previously submitted English language versions of the International Search Report (citing these references) with the IDS's of February 1, 2006 and August 8, 2006 to comply with US practice.

Based on the above, it is believed that Applicants have complied with the requirements for submitting foreign language references for the IDS's of February 1, 2006 and August 8, 2006.

Thus, kindly consider the references listed on the IDS's of February 1, 2006 and August 8, 2006 and return an Examiner-initialed copy of PTO-1449 forms indicating such.

III. INDEFINITENESS REJECTION

Claims 1-2 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the reasons on page 3 of the Office Action. This rejection is respectfully traversed.

To start, it is well established that a product-by-process claim, which is a product claim that defines the claimed product in terms of the process by which it is made, is proper. In re Luck, 476 F.2d 650, 177 USPQ 523 (CCPA 1973); In re Pilkington, 411 F.2d 1345, 162 USPQ 145 (CCPA 1969); In re Steppan, 394 F.2d 1013, 156 USPQ 143 (CCPA 1967). A claim to a device, apparatus, manufacture, or composition of matter may contain a reference to the process in which it is intended to be used without being objectionable under 35 USC 112, second paragraph, so long as it is clear that the claim is directed to the product and not the process. In the instant case, it is clear that claims 1-2 and are directed to the product itself and not the process.

Further, definiteness of claim language is analyzed, not in a vacuum, but in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. In re Moore, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971). See also, M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2173.02.

The specification describes in detail what lactoperoxidase is, how to obtain it, and procedures for digesting it with a protease as claimed. See for instance, page 6-7, and the working example of digesting it in Example 2 on page 11. Based on such, it is believed that the skilled artisan would clearly understand the metes and bounds of "digestion product thereof."

Nonetheless, Applicants have amended the claims to further define and clarify the claimed subject matter: (1) to specify the functional property of the said lactoperoxidase and/or digestion product of osteogenesis promoting effect (claims 1-2); the proteases used for digestion (claims 3 and 6); (3) the molecular weights of the digestion products (claims 4 and 7); and (4) the effective dosages to obtain the osteogenesis promoting effect (claims 5 and 8).

Based on the above, it is believed that the claims are clear, definite and have full antecedent basis. The rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

IV. ANTICIPATION REJECTION

Claims 1-2 were rejected under 35 U.S.C. § 102(b) as anticipated by KATO (US 5,932,259) for the reasons on pages 3-4 of the Office Action. This rejection is respectfully traversed.

Amended claims 1 and 2 clearly recite that "said lactoperoxidase and/or digestion product has an osteogenesis promoting effect." Accordingly, the amended claims clearly identify that the lactoperoxidase and/or digestion product are the effective components exhibiting the osteogenesis promoting effect. The rejection should fall, because KATO fails to disclose or suggest this feature of claims 1 and 2, namely that lactoperoxidase, or a digestion product, has an osteogenesis promoting effect.

Instead, KATO discloses a basic protein derived from milk that has bone reinforcing effects. This basic protein derived from milk contains numerous components. Lactoperoxidase is identified as one component of this basic protein fraction derived from milk. However, KATO never mentions that lactoperoxidase by itself, or a digestion product thereof, has an osteogenesis promoting effect. Indeed, KATO never identifies any particular component as necessary for the functional activity.

By contrast, the present invention is based on the discovery that lactoperoxidase (LPO), or its digestion product, has the osteogenesis promoting effect among the basic fractions. Indeed, prior to the instant invention it had not been known that lactoperoxidase by itself, or a digestion product thereof, had the osteogenesis promoting effect. See, the discussion in the instant specification at page 4, lines

19-22, wherein it is disclosed that "the fact that lactoperoxidase has an osteoblast differentiation promoting effect has not been clarified yet, and therefore lactoperoxidase is not used for bone strengthening." See also, the disclosure at page 5, lines 5-6, which states: "it is not known that lactoperoxidase contained in the basic proteins has an osteogenesis promoting effect."

For this reason, the rejection should be withdrawn, because it is clear that KATO fails to disclose each and every element of claims 1 and 2.

In addition, KATO fails to disclose "lactoperoxidase having a purity of at least 91%" as required by amended claims 1 and 2. Indeed, KATO never specifies a level of purity of lactoperoxidase.

Also, according to the present application, the necessary dose for promoting osteogenesis of the lactoperoxidase having a purity of at least 91% is 10 mg/day, when lactoperoxidase is used in place of the basic protein fraction, such as that in KATO. By contrast, KATO discloses that the necessary dose for the basic protein fraction is 0.5 g (500 mg)/day to promote osteogenesis (column 4, line 59). Thus, it is clear that KATO fails to disclose that "the effective dose of said lactoperoxidase and/or digestion product needed to obtain the osteogenesis promoting effect is

approximately 10 mg/day" as recited in dependent claims 5 and 8.

Lastly, it should be noted that new independent claims 9 and 10 have been added that correspond to claims 1 and 2 but are in "consisting essentially of" format. Such claims exclude the extra components found in the basic protein fraction of KATO (as shown in column 3, lines 10-20 and Table 2 in column 5).

For these reasons, it is believed that independent claims 1 and 2 and all claims dependent thereon are novel over KATO. Thus, the 102(b) anticipation rejection over KATO is untenable and should be withdrawn.

V. CONCLUSION

In view of the above, it is respectfully submitted that the application is in condition for allowance and notice to that effect is hereby requested. If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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